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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/598,149   | 04/17/2007  | Elliot L. Chaikof    | 11-04               | 1649             |
| 23713  | 7590        | 01/25/2010           | EXAMINER            |                  |
| GREENLEE WINNER AND SULLIVAN P C<br>4875 PEARL EAST CIRCLE<br>SUITE 200<br>BOULDER, CO 80301 |             |                      | ROBINSON, HOPE A    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1652                |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 01/25/2010          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/598,149             | CHAIKOF ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | HOPE A. ROBINSON       | 1652                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 November 2009.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20,23 and 24 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 3 is/are allowed.
- 6) Claim(s) 4 and 16 is/are rejected.
- 7) Claim(s) 1,2,5-15,17-20,23 and 24 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 April 2009 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

**DETAILED ACTION**

***Application Status***

1. Applicant's response to the Office Action mailed August 3, 3009 on November 6, 2009, is acknowledged.

***Claim Disposition***

2. Claims 1-20 and 23-24 are pending. Claims 1-5, 16-20 and 23-24 are under examination. Claims 6-15 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention.

***Claim Objection***

3. Claims 1-2 and 5 are objected to because of the following informalities:

For clarity and precision of claim language, it is suggested that claim 1 is amended to read,

“A truncated thrombomodulin protein set forth in SEQ ID NO:3, comprising:

- a) epidermal growth factor (EGF)-like domains (4-6);
- b) a substitution of leucine to methionine at position 40 of SEQ ID NO:3; and
- c) a GGM amino acid motif appended at a carboxy terminus of said truncated thrombomodulin protein”. The dependent claims are included in this.

Claims 1-2, 5, 16-20 and 23-24 5 is objected to as depending on a rejected based claim.

Correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a truncated thrombomodulin derivative conjugate and a polymer. The claim does not establish what is intended by "polymer". Thus the claims are drawn to a genus of "polymer materials. The specification describes the polymer as branched or linear and mentions PEG. However, the limitations of the specification cannot be read into the claims. The art generally recognizes that a polymer can be a nucleic acid or a protein, etc., thus absent adequate guidance the claims read on any art recognized polymer, a large variable genus.

The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire

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genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

***Response to Arguments***

5. Applicant's comments have been considered in full. Note that the rejections of record are withdrawn. Thus, applicant's comments are moot and will not be discussed herein. Note also that a new ground of rejection is instituted under 35 USC 112, first paragraph for the reasons set forth above.

***Conclusion***

6. Claim 3 is allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652